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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,111	09/23/2005	Donald Leonard Nicholas Cardy	056222-5068-US	6575

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EXAMINER	
THOMAS, DAVID C	
ART UNIT	PAPER NUMBER
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,111	CARDY ET AL.	
	Examiner	Art Unit	
	David C. Thomas	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 27-44* is/are pending in the application.

4a) Of the above claim(s) *40-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 27-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12 January 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1, 2, and 27-39, in the reply filed on December 21, 2006 is acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 27-35, and 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Kozwich et al. (U.S. Patent No. 6,153,425).

Kozwich teaches a self-contained lateral flow assay device to test for the presence and/or amount of a nucleic acid sequence of interest in a sample (for overview, see column 4, lines 3-17 and 33-41) comprising:

(a) a sample receiving zone for contacting the device with a sample to be tested (sample is added through open end of top cylinder, column 7, lines 36-44 and lines 58-61 and Figure 1A and B, upper elongated and tapered chamber, part 2);

(b) an extraction zone for extraction of nucleic acid from the sample (extraction takes place in upper chamber after closing lid with sealing lip in place preventing contact with lower chambers, column 7, lines 58-61 and column 8, lines 16-17; top cylinder is rotated to allow lysis buffer used in extraction to flow into collection reservoir through aperture, column 7, lines 61-63, column 8, lines 18-19, and Figure 1B, parts 13 and 16);

(c) a nucleic acid amplification zone in liquid communication with the sample receiving zone (amplification occurs in upper chamber where sample is added after closing lid with sealing lip in place preventing contact with lower chambers, column 7, lines 58-61 and column 8, lines 16-17; top cylinder is rotated to allow wash buffers used in amplification step to flow into collection reservoir through aperture, column 7, lines 61-63, column 8, lines 18-19, and Figure 1B, parts 13 and 16); and

(d) a detection zone for detecting the product/s, directly or indirectly, of a nucleic acid amplification reaction performed in the nucleic acid amplification zone (detection takes place in lower chamber containing pad and detection strip, column 7, lines 44-47, Figure 1C, part 20, and Figure 2C, parts 9 and 10), said detection zone being in liquid communication with the amplification zone (the detection chamber is in fluid communication with the upper, amplification chamber when the upper chamber is rotated to allow sample to contact pad in lower chamber, column 7, line 64 to column 8, line 1, column 8, lines 20-29, Figure 1C, part 20 and Figure 2C, parts 9 and 10); the device also comprising a porous matrix which, at a proximal end, is in liquid communication with the sample receiving zone such that liquid applied to the sample receiving zone flows along the device through the porous matrix by capillary action (the detection chamber contains absorbent pad and detection strip made of nitrocellulose or other material that receives sample by wicking action from upper chamber when aperture of upper chamber is positioned over detection chamber by rotation to allow sample to contact pad in lower chamber, column 7, line 64 to column 8, line 1, column 8, lines 20-29 and 45-49, Figure 1C, part 20 and Figure 2C, parts 9 and 10).

With regard to claim 2, Kozwich teaches a lateral flow assay device wherein the nucleic acid amplification comprises an isothermal amplification reaction (amplification can be performed by isothermal processes such as NASBA, column 11, lines 17-28, or strand displacement amplification (SDA), column 12, lines 13-18).

With regard to claim 27, Kozwich teaches a lateral flow assay device wherein the device comprises one or more reagents releasably bound on the porous matrix (colored microparticles are immobilized on detection strip that are coated with receptors for target sample containing haptens, and the complex of micoparticles and target sample travel down or up strip to capture zone for viewing color band, column 8, line 63 to column 9, line 3 and column 9, lines 40-47 and Figure 6, part 24, region of immobilized micropartcles and parts 25-26, capture zones).

With regard to claim 28, Kozwich teaches a lateral flow assay device wherein the one or more reagents releasably bound comprise one or more reagents required to perform the nucleic acid amplification reaction (amplified target contains primers used in amplification process and are bound to immobilized microparticles before wicking down strip to capture area, column 9, lines 40-47, column 11, lines 29-36, Figure 6 and Figures 8 and 9).

With regard to claims 29 and 30, Kozwich teaches a lateral flow assay device comprising one or more reagents immobilized on the porous matrix (detection strip contains microparticles immobilized in region of strip that binds to and captures amplified target sample containing haptens after wicking onto strip after amplification in

reaction chamber, column 8, lines 63-65 and Figure 6, part 24 and column 9, lines 41-44).

With regard to claim 31, Kozwich teaches a lateral flow assay device comprising a probe comprising nucleic acid releasably bound or immobilized on the porous matrix (probes used in cycling probe detection bind to microparticles when target is not present to produce signal indicating no target is present by binding in capture zone of strip, column 13, lines 27-37, column 14, lines 4-14 and Figure 12).

With regard to claim 32, Kozwich teaches a lateral flow assay device wherein the sample receiving zone comprises reagents suitable to perform a nucleic acid extraction step on a sample applied to the sample receiving zone (sample is first introduced into upper chamber containing reagents for extraction process, column 9, lines 16-25 and column 15, line 63 to column 16, line 8).

With regard to claim 33, Kozwich teaches a lateral flow assay device comprising a matrix comprising one or more agents for cell lysis and nucleic acid protection (upper chamber contains dry lysing reagents for extraction of nucleic acids that are resuspended in the buffer containing the sample, column 9, lines 16-25).

With regard to claim 34, Kozwich teaches a lateral flow assay device comprising means for interruption of flow, alteration of rate of flow, or alteration of flow path, of a liquid along the porous matrix within the device (flow of amplification target samples along strip will be interrupted when then reach capture zone to form visible dye line, column 9, lines 41-48 and Figure 6; flow of liquid onto strip can be stopped by rotation of upper cylinder relative to lower detection chamber such that aperture between

chambers is sealed, such as in position A, column 7, line 64 to column 8, lines 6 and Figure 1A).

With regard to claim 35, Kozwich teaches a lateral flow assay device comprising means for altering the relative positions of two or more portions of the porous matrix, so as to affect the rate of flow of liquid from one portion to another (microparticles containing receptors for hapten can be located in different positions of porous matrix, such as within pad, or in locations directly on strip, column 18, lines 13 to 18 and Figure 19, parts 39 and 58).

With regard to claim 37, Kozwich teaches an assay kit for performing an assay to test for the presence and/or amount of a nucleic acid sequence of interest in a sample, the kit comprising a lateral flow assay device according to claim 1, and a supply of at least one reagent required to perform the assay (lateral flow device includes an amplification reaction bead in a reaction bead chamber located in hinged cover of device, column 9, lines 28-32 and Figure 4, parts 11 and 12; extraction reagents are located in upper chamber for extracting samples added to upper chamber, column 9, lines 17-19).

With regard to claim 38, Kozwich teaches an assay kit comprising a supply of carrier liquid (water or buffer washes are provided to wash extracted nucleic acid bound to solid phase, column 9, lines 22-26; water is added to resuspend enzymes for amplification step, column 9, lines 27-36, followed by elution of amplified sample into detection chamber, column 9, lines 37-40).

With regard to claim 39, Kozwich teaches an assay kit wherein at least one reagent is provided dissolved and/or suspended in the carrier liquid (lysis buffer can either be in dry form and resuspended in liquid from sample, column 9, lines 17-19 or can be in liquid form, column 16, line 66 to column 17, line 4).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kozwich et al. (U.S. Patent No. 6,153,425) in view of Cardy et al. (WO 93/06240).

Kozwich teaches the limitations of claims 1, 2, 27-35, and 37-39 as discussed above.

Kozwich does not teach a lateral flow assay device wherein the amplification reaction comprises a SMART amplification reaction involving the sequence of interest in the formation of a three-way junction with two probe molecules.

Cardy teaches a SMART amplification reaction for testing for the presence of a nucleic acid sequence of interest in a sample comprising contacting the sample with a first and second probes such that the probes hybridize at substantially adjacent regions of the target and such that non-complementary portions of probes are annealed to each other to form three-way junction (p. 4, lines 21-31 and Figure 1, top).

Cardy does not teach a self-contained lateral flow device to test for the presence and/or amount of nucleic acid sequence of interest in a sample comprising sample receiving, extraction, amplification, and detection zones.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the self-contained lateral flow device of Kozwich with a SMART amplification reaction as taught by Cardy since the SMART method is easily compatible with the lateral flow device of Kozwich since it is powerful and sensitive assay wherein the reagents can be placed in chambers the lateral flow device for release into the reaction chamber to react with target nucleic acid following extraction. Thus, an ordinary practitioner would have been motivated to use an alternative amplification process such as the SMART amplification reaction since this assay is highly sensitive and accurate, since extended probes will only be formed and detected in the presence of the sequence of interest (p. 6, lines 5-11). The SMART assay products can be easily amplified by any number of processes including

isothermal processes to increase the signal (p. 6, lines 12-22), wherein such reagents can also be placed in the self-contained device, including primers containing the required haptens for detection during the lateral flow detection step.

Conclusion

7. Claims 1, 2, and 27-39 are rejected. No claims are allowable.

Correspondence

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Thomas whose telephone number is 571-272-3320 and whose fax number is 571-273-3320. The examiner can normally be reached on 5 days, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David C. Thomas 3/6/07

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Art Unit 1637

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PRIMARY EXAMINER
3/6/07